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EXALGO[®] (hydromorphone HCl)
Extended-Release Tablets CII

EXALGO Proposed Risk Mitigation Strategy
Including
EXALGO Risk Evaluation and Mitigation Strategy (REMS)

31 January 2012

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1. EXALGO RISK MITIGATION STRATEGY EXECUTIVE SUMMARY

A comprehensive risk mitigation strategy, including the EXALGO Risk Evaluation and Mitigation Strategy (REMS), has been implemented to ensure that the benefits of EXALGO outweigh the risks. An updated risk mitigation strategy will be used to support the approval of the 32 mg tablet, including revising all material to include the 32 mg dosage strength and associated risks. All EXALGO prescribers will be educated on this new content. In addition, a revised and comprehensive assessment program is proposed to confirm the effectiveness of the EXALGO REMS and to ensure that outcomes in patients taking the 32 mg tablet strength are consistent with the safety profile demonstrated for the lower EXALGO dosage strengths.

The risk mitigation strategy includes healthcare professional (HCP) and patient education on the risk-benefit profile and safe use of EXALGO. This risk mitigation strategy includes the EXALGO REMS components, additional education and outreach of the EXALGO REMS content, EXALGO-specific education tools and activities, and tools and general opioid prescribing education and safe use tools and activities.

The goals of the EXALGO Risk Mitigation Strategy Program are as follows:

1. To inform patients and healthcare professionals about the potential for abuse, misuse, overdose, and addiction of EXALGO.
2. To inform patients and healthcare professionals about the safe use of EXALGO.
3. To inform patients and healthcare professionals about the risks, appropriate prescribing, and safe use of prescription opioid analgesics.

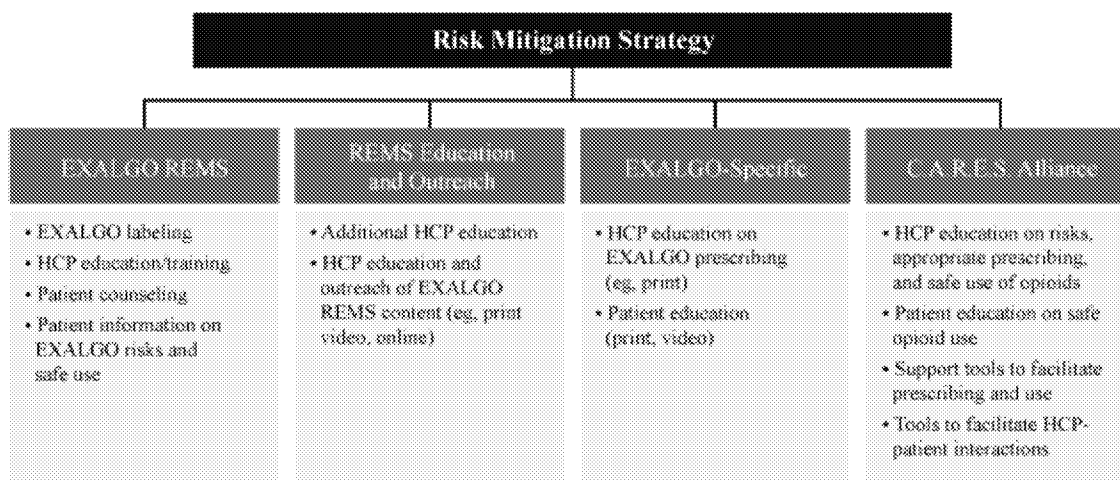
The comprehensive risk mitigation strategy is designed to facilitate appropriate prescribing by HCPs and safe use by patients. The strategy provides education and support tools to aid patient selection, dosing and administration, periodic evaluation, and patient counseling throughout the duration of care. The program also provides various tools to encourage and facilitate interactions between HCPs and patients. These tools are designed for practical use at the individual HCP and patient levels.

The overall EXALGO Risk Mitigation Strategy Program contains 4 major components:

1. EXALGO REMS
 - ∞ Provides education to EXALGO prescribers on EXALGO risks, appropriate prescribing, and safe use
 - ∞ Provides information to patients on safe use of EXALGO
2. EXALGO REMS Education and Outreach
 - ∞ Provides additional tools and outreach activities intended to increase stakeholder education, comprehension, and implementation of EXALGO REMS education content and safe use conditions
3. EXALGO-Specific Risk Mitigation Tools and Activities
 - ∞ Provides additional education and outreach activities for EXALGO risks, appropriate prescribing (e.g., proper dosing and administration), and safe use
 - ∞ Provides continuous support to EXALGO HCPs from experts in opioid and EXALGO prescribing
 - ∞ Provides patients with information on EXALGO risks and safe use
4. Appropriate Opioid Prescribing and Safe Use Through the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) AllianceSM Program
 - ∞ Provides HCPs (including allied HCPs), pharmacists, and patients with education and support tools to facilitate appropriate opioid prescribing, dispensing, and use, including tools for identifying appropriate patients, patient counseling, appropriate dosing and administration, assessing treatment effectiveness, and appropriateness for continued treatment

The schematic below depicts the 4 major elements of the EXALGO Risk Mitigation Strategy Program design (**Figure 1**).

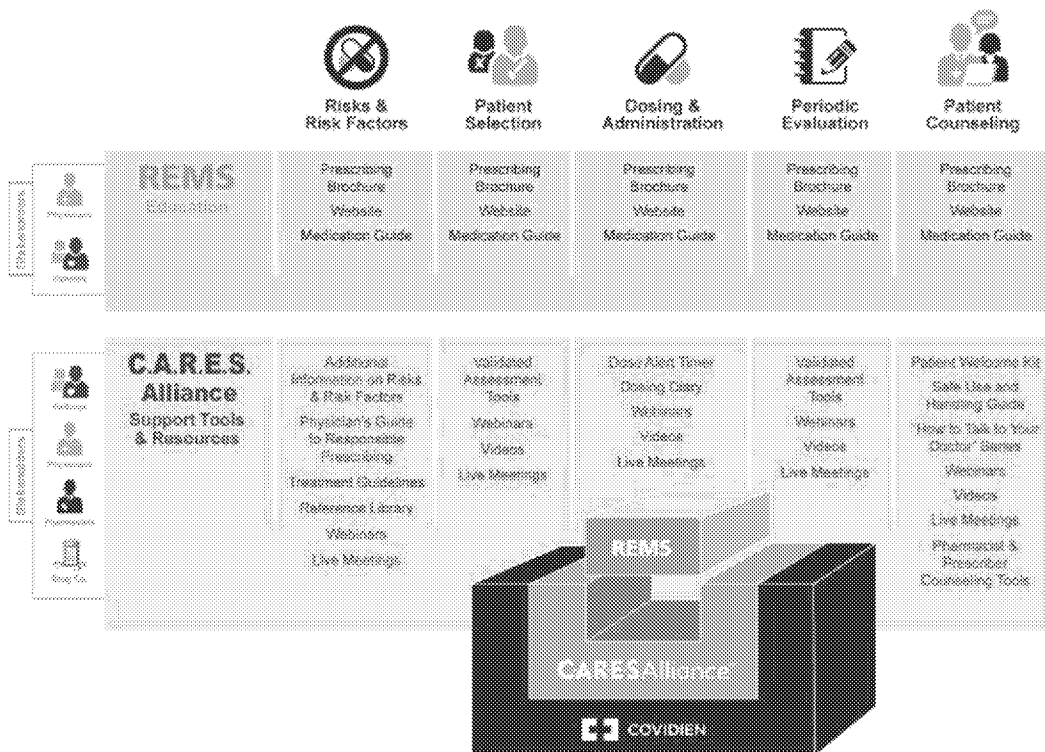
Figure 1: EXALGO Risk Mitigation Strategy Program Elements



EXALGO® (hydromorphone HCl) Extended-Release Tablets, CII
Risk Mitigation Strategy Overview**Mallinckrodt Inc.**

The content of this risk mitigation strategy emphasizes topics necessary for appropriate prescribing of EXALGO, such as risks, patient selection, dosing and administration, periodic evaluation, patient counseling, and safe use. **Figure 2** provides a graphic depiction of the primary content of the EXALGO Risk Mitigation Strategy Program and examples of tools that deliver this content.

Figure 2: Overview of EXALGO Risk Mitigation Strategy Content for Healthcare Professionals

**1.1 Interim REMS and Extended-Release and Long-Acting Opioid Class-wide REMS**

Mallinckrodt will execute the EXALGO Interim REMS, as outlined in the Proposed REMS and REMS Supporting Document and summarized in this document, until the approval of the extended-release (ER) and long-acting (LA) opioid class-wide REMS. Upon approval of the ER/LA opioid class-wide REMS the EXALGO REMS tools and activities will be modified accordingly. Until then, however, the interim REMS components and activities will be modified for the approval of the 32 mg tablet strength. Mallinckrodt will train all EXALGO prescribers on the modified REMS education as outlined in the Healthcare Professional Education Program Kit, including those who have been educated on the original content since the initial approval of the EXALGO REMS.

As is currently the case, the required REMS components will be supported by a comprehensive risk mitigation strategy that contains many tools and activities to educate HCPs and patients on EXALGO risks, appropriate prescribing, and safe use. These activities will be supported by

additional education and outreach activities on the EXALGO REMS content, additional EXALGO-specific tools and activities, as well as a comprehensive education and outreach program for appropriate opioid prescribing and safe use.

Mallinckrodt will continue these additional risk mitigation tools and activities after approval of the ER/LA opioid class-wide REMS.

1.2 EXALGO REMS

Upon approval of the 32 mg dosage strength, updated EXALGO REMS education and outreach materials will be used to educate HCPs and patients on the EXALGO risk-benefit profile, appropriate prescribing, and safe use. Education and outreach will occur via multiple media, including print (e.g., HCP EXALGO REMS Education Program, Dear Healthcare Professional Introductory Letter, Prescribing Brochure), online information and resources (e.g., www.exalgorems.com), and personal communications (e.g., field-force interactions, live meetings, webinars, congress activities, live or telephone interactions). **Table 1** provides an overview of the EXALGO REMS education tools that will be available for each stakeholder.

Table 1: EXALGO Labeling and EXALGO REMS Components

Risk Mitigation Tool or Activity	Stakeholder	
	Prescribers	Patients
Labeling		
∞ Full Prescribing Information ^a	X	
∞ Bottle Label ^a	X	X
∞ Medication Guide ^a	X	X
Healthcare Professional Education Program Kit ^a		
∞ Full Prescribing Information/Medication Guide ^a	X	X
∞ Dear Healthcare Professional Introductory Letter ^a	X	
∞ Prescribing Brochure ^a	X	
∞ Education Confirmation Form ^a (ECF)	X	
∞ Safe Use and Handling Guide ^b		X
Online Resources		
∞ www.exalgorems.com website ^a	X	X
∞ www.exalgo.com website ^a	X	X

^a Existing tool/activity that will be modified and repeated upon approval of the 32 mg tablet strength.

^b New tool/activity that will be available upon approval of the 32 mg tablet strength.

See Appendix A for additional information on EXALGO REMS tools and activities.

1.3 EXALGO REMS Education and Outreach Activities

In addition to the required REMS components, the EXALGO REMS education content will be delivered through additional education and outreach activities. These activities are designed to ensure that EXALGO prescribers and allied HCPs are educated on the EXALGO REMS education program, to ensure that pharmacists are aware of the EXALGO REMS program components and content, and to facilitate patient and caregiver education and counseling. This education and outreach will occur via multiple media, including print and video, online information and resources (e.g., www.exalgo.com), and personal communications (e.g., live meetings, webinars, video, congress activities, live or telephone interactions). **Table 2** provides an overview of the additional EXALGO REMS education and outreach.

Table 2: EXALGO REMS Education and Outreach Activities

Risk Mitigation Tool or Activity	Stakeholder		
	Prescribers ^a	Pharmacists	Patients ^b
Print and Video			
∞ Full Prescribing Information/Medication Guide ^c	X	X	X
∞ Bottle Label ^c	X	X	X
∞ Healthcare Professional Education Program Kit ^c	X		
– Dear Healthcare Professional Introductory Letter ^c	X		
– Prescribing Brochure ^c	X		
– ECF ^c	X		
– Safe Use and Handling Guide ^d			X
∞ Education Escalation Program ^c	X		
∞ EXALGO REMS Education Videos ^c	X		
∞ Pharmacist Communication Plan ^d		X	
– Dear Pharmacist Introductory Letter ^c		X	
– Prescribing Brochure ^c		X	
– EXALGO Dispensing Checklist ^d		X	
∞ Medication Guide Tear Pad ^c		X	X
Personal Communications			
∞ REMS Train-the-Trainer Meeting ^c	X	X	
∞ EXALGO REMS Education Webinars ^c	X		
Online Resources			
∞ www.exalgorems.com website ^c	X	X	X
∞ www.exalgo.com website ^c	X	X	X

^a Includes allied HCPs.^b Includes caregivers.^c Existing tool/activity that will be modified and repeated upon approval of the 32 mg tablet strength.^d New tool/activity that will be available upon approval of the 32 mg tablet strength.

See Appendix B for additional information on EXALGO REMS education and outreach and activities.

1.4 EXALGO-Specific Risk Mitigation Tools and Activities

EXALGO REMS education and outreach activities will be supplemented by tools and activities to facilitate appropriate prescribing and safe use of EXALGO. Education materials and outreach activities will be used to further inform HCPs, pharmacists, and patients on the EXALGO risk-benefit profile, appropriate prescribing, and safe use. Education and outreach will occur via multiple media, including print (e.g., brochures), online information and resources (e.g., www.exalgo.com), and personal communications (e.g., field-force interactions, congress participation). **Table 3** provides an overview of the education and communication tools that will be available for each stakeholder.

Table 3: EXALGO-Specific Risk Mitigation Tools and Activities

Risk Mitigation Tool or Activity	Stakeholder		
	HCPs ^a	Pharmacists	Patients ^b
Print and Video			
∞EXALGO Dosing and Administration Guide ^c	X		
∞Patient Starter Kit and Video ^c			X
Personal Communications			
∞Congress Booth Activities ^c	X	X	
∞Expert-on-Call Program ^c	X	X	
∞Mallinckrodt Product Monitoring ^c	X	X	X
∞EXALGO Speaker Bureau ^c	X	X	
Online Resources			
∞ www.exalgo.com website ^c	X	X	X
∞Answers to Important Questions ^c			X
∞Patient Introductory Video ^c			X

^a Includes prescribers and allied HCPs.

^b Includes caregivers.

^c Existing tool/activity that will be modified and repeated upon approval of the 32 mg tablet strength. See Appendix C for additional information on EXALGO-specific risk mitigation tools and activities.

1.5 General Opioid Risk Mitigation Tools and Activities

Safe and effective therapy for the management of chronic noncancer pain requires clinical skills and knowledge of the principles of good opioid prescribing and the assessment and management of risks associated with opioids (Chou et al, 2009). Therefore, the overall risk mitigation strategy includes extensive resources, education, and support tools for general risks, appropriate prescribing, and safe use of prescription opioid analgesics. Education and outreach will occur via multiple media, including print and video (e.g., brochures, videos), online information and resources, and personal communications (e.g., live meetings, webinars, live or telephone interactions). **Table 4** provides an overview of the education and communication tools that will be available for each stakeholder.

Table 4: General Opioid Risk Mitigation Tools and Activities

Risk Mitigation Tool or Activity	Stakeholder		
	HCPs ^a	Pharmacists	Patients ^b
Print and Video			
∞ Opioid Clinical Management Guide ^c	X	X	
∞ Opioid Clinical Management Checklist ^c	X		
∞ <i>Responsible Opioid Prescribing: A Physician's Guide</i> ^c	X		
∞ <i>Opioid Prescribing Toolkit</i> ^c	X		
∞ Ask-an-Expert Video: Risk Stratification ^c	X		
∞ Ask-an-Expert Video: Prescribing Considerations ^c	X		
∞ APS/AAPM Opioid Treatment Guidelines Reprint Carrier ^c	X		
∞ Urine Drug Screening Reprint Carrier ^c	X		
∞ Universal Precautions in Pain Medicine Reprint Carrier ^c	X		
∞ Urine Drug Testing Brochure ^c	X		
∞ Patient-Prescriber Expectations and Responsibilities Form ^c	X		X
∞ Validated Pain Assessment Tools ^c	X		X
∞ Validated Risk Assessment Tools ^c	X		X
∞ Validated Abuse Monitoring Tools ^c	X		X
∞ Opioid Safe Use and Handling Guide ^c			X
– My Meds Card ^c	X	X	X
– Safe Use and Handling Card ^c			X
∞ How to Talk to Your Doctor Brochure ^c	X		X
∞ Pain Management Journal ^c	X		X
∞ Pain Management Guide for Older Adults ^c			X
– My Medications Card ^c	X	X	X
∞ <i>Defeat Chronic Pain Now!</i> ^c			X
∞ Pharmacist's Manual ^c		X	
∞ VIGIL Pharmacist Toolkit ^c		X	
∞ VIGIL Education and Implementation Video ^c		X	
Personal Communications			
∞ Train-the-Trainer Meeting ^d	X	X	
∞ Opioid Prescribing Outreach ^d			
– Congress Booth Activities ^d	X	X	
– Independent Medical Education ^c	X	X	
Online Resources			
∞ www.caresalliance.org website ^a	X	X	X
∞ American Chronic Pain Association Patient Resources			X

^a Includes prescribers and allied HCPs.^b Includes caregivers.^c Existing tool/activity that will be continued.^d Existing tool/activity that will be modified and repeated upon approval of the 32 mg tablet strength.

See Appendix D for additional information on general opioid risk mitigation tools and activities.

APS = American Pain Society; AAPM = American Academy of Pain Medicine; VIGIL = Verification, Identification, Generalization, Interpretation, Legalization.

1.6 Assessment of Program Performance and Patient Outcomes

Mallinckrodt will employ extensive program assessment and monitoring to assess the performance of the EXALGO REMS and overall risk mitigation strategy to determine whether the risk mitigation strategy is meeting its goals (**Table 5**). Mallinckrodt, along with the standing EXALGO REMS Safety Advisory Board, will continue to ensure that the risk mitigation strategy is adequately addressing the stated goals and ensure the risk-benefit balance in patients taking EXALGO. Mallinckrodt will continue to implement a continuous process improvement approach to ensure the risk-benefit balance of EXALGO.

Table 5: Continuing Assessment and Monitoring Methods

Outcome	KAB Survey ^b	PVG ^b	FDA AERS ^a	RADARS ^a	AAPCC ^{a,c}	Media & Internet ^b	Claims ^b
Appropriate prescribing	X	X	X	X	X	X	X
Safe use	X	X	X	X	X	X	
Fatal overdose		X	X	X	X	X	
Nonfatal overdose		X	X		X	X	
Pediatric exposure		X	X		X		
Accidental ingestion		X	X		X	X	
Inappropriate prescribing	X	X	X		X		X
Misuse	X	X	X		X	X	X
Abuse	X	X	X	X		X	
Addiction	X	X	X	X		X	
Diversion		X	X	X		X	

^a Existing tool/activity that will be modified and repeated upon approval of the 32 mg tablet strength.

^b Existing tool/activity that will be continued.

^c The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS[®]) obtains poison control data directly from the participating poison control centers with detailed case notes.
FDA AERS = US Food and Drug Administration Adverse Event Reporting System; PVG = pharmacovigilance; AAPCC = American Association of Poison Control Centers; RADARS = Researched Abuse, Diversion and Addiction-Related Surveillance; KAB = Knowledge, Attitude, and Behavior.

Appropriate prescribing is a key element of safe use of EXALGO, and particularly the use of the 32 mg tablet. Reducing the risk of unintentional overdose requires proper patient selection (e.g., use only in opioid-tolerant patients) and proper dosing and administration (e.g., appropriate conversion and titration) as outlined in the Full Prescribing Information and EXALGO REMS education information. Mallinckrodt will employ enhanced monitoring and assessment activities to confirm appropriate prescribing of the 32 mg tablet. Mallinckrodt will employ serial chart studies to obtain information on appropriate prescribing and safe use.

Mallinckrodt is willing to work with the FDA on designing an observational study evaluating the incidence of abuse, misuse, addiction, and overdose in patients taking 32 mg/day EXALGO. If such an observational study is required for the approval of the 32 mg strength, Mallinckrodt will ensure the study design is compliant with all current regulations and guidance.

In summary, the approval and availability of the 32 mg tablet strength will be supported by a comprehensive risk mitigation strategy to support appropriate prescribing and safe use as well as to ensure patient outcomes (**Table 6**). The program also includes comprehensive assessment and monitoring and an independent REMS safety advisory board tasked with evaluating all assessment and monitoring data as well as the results of the potential postapproval study and making recommendations for the most appropriate steps to protect patient safety. The sections below provide additional detail on the specific risk mitigation tools and activities.

Table 6: Summary of EXALGO Risk Mitigation Strategy Tools and Activities

Tool or Activity	Continued	Modified and Repeated	New
REMS			
∞Medication Guide		X	
∞Healthcare Professional Education Program Kit		X	
– Safe Use and Handling Guide			X
∞Online Resources		X	
REMS Education and Outreach			
∞Medication Guide Tear Pad		X	
∞Prescriber REMS Education and Outreach		X	
– Education Escalation Program		X	
– Education Videos		X	
– Regional Education Events			X
– Education Congress Activities		X	
∞Pharmacist Communication Plan			
– Dear Pharmacist Introductory Letter		X	
– Prescribing Brochure		X	
– EXALGO Dispensing Checklist			X
∞Online Resources		X	
EXALGO-Specific			
∞EXALGO Dosing and Administration Guide		X	
∞Patient Starter Kit and Video		X	
∞Expert-on-Call Program		X	
∞Mallinckrodt Product Monitoring		X	
∞Online Resources		X	
C.A.R.E.S Alliance			
∞Education and Outreach		X	
∞Online Resources		X	
Assessment and Monitoring			
∞Mallinckrodt Pharmacovigilance	X		
∞FDA AERS	X		
∞Media & Internet Monitoring	X		
∞RADARS (including AAPCC)	X		
∞KAB Survey	X		
∞Claims Data	X		
∞Chart Study			X
∞Additional Postapproval Evaluation and Study			X

FDA AERS = US Food and Drug Administration Adverse Event Reporting System; RADARS = Researched Abuse, Diversion, and Addiction-Related Surveillance; AAPCC = American Association of Poison Control Centers; KAB = Knowledge, Attitude, and Behaviors.

2. REQUIRED EXALGO REMS COMPONENTS

2.1 Full Prescribing Information

The EXALGO Full Prescribing Information communicates information about EXALGO risks as well as information about mitigating these risks such as proper patient selection and dosing and administration. The EXALGO prescribing information also includes information to aid HCPs in counseling patients on safe use. In addition, the EXALGO prescribing information contains a Boxed Warning that highlights the most important of this information (**Figure 3**). The EXALGO prescribing information is attached to each bottle and is also provided with all educational material for HCPs. In addition, HCPs may access the Full Prescribing Information through the www.exalgo.com and www.exalgorems.com websites.

Figure 3: EXALGO Boxed Warning

Please see full prescribing information including **BOXED WARNING**.

PHYSICIANS AND OTHER HEALTHCARE PROVIDERS MUST BECOME FAMILIAR WITH THE IMPORTANT WARNINGS IN THIS LABEL.

<p style="text-align: center;">WARNING: POTENTIAL FOR ABUSE, IMPORTANCE OF PROPER PATIENT SELECTION AND LIMITATIONS OF USE</p> <p>Potential for Abuse EXALGO contains hydromorphone, an opioid agonist and a Schedule II controlled substance with an abuse liability similar to other opioid analgesics. EXALGO can be abused in a manner similar to other opioid agonists, legal or illicit. These risks should be considered when administering, prescribing, or dispensing EXALGO in situations where the healthcare professional is concerned about increased risk of misuse, abuse, or diversion. Schedule II opioid substances which include hydromorphone, morphine, oxycodone, fentanyl, oxymorphone and methadone have the highest potential for abuse and risk of fatal overdose due to respiratory depression.</p> <p>Proper Patient Selection EXALGO is an extended release formulation of hydromorphone hydrochloride indicated for the management of moderate to severe pain in opioid tolerant patients when a continuous around-the-clock opioid analgesic is needed for an extended period of time. Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day or an equianalgesic dose of another opioid, for a week or longer. EXALGO is for use in opioid tolerant patients only. Fatal respiratory depression could occur in patients who are not opioid tolerant. Accidental consumption of EXALGO, especially in children, can result in a fatal overdose of hydromorphone.</p> <p>Limitations of Use EXALGO is not indicated for the management of acute or postoperative pain. EXALGO is not intended for use as an as-needed analgesic. EXALGO tablets are to be swallowed whole and are not to be broken, chewed, dissolved, crushed or injected. Taking broken, chewed, dissolved or crushed EXALGO or its contents leads to rapid release and absorption of a potentially fatal dose of hydromorphone.</p>
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The EXALGO prescribing information includes considerable information to guide appropriate patient selection, including the specific indication and contraindications (**Figure 4**).

Figure 4: EXALGO Indication and Contraindications

□

EXALGO is an extended-release oral formulation of hydromorphone hydrochloride indicated for the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time.

Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day or an equianalgesic dose of another opioid, for a week or longer.

EXALGO is NOT intended for use as an as-needed analgesic.

EXALGO is not indicated for the management of acute or postoperative pain.

The EXALGO prescribing information also includes considerable information for prescribers to counsel patients on the safe use of EXALGO (see **Figure 5** for patient counseling messages).

Figure 5: Patient Counseling Information (selected)

□

- ∞ EXALGO is for use only in patients who are already receiving opioid pain medicine and their body is used to taking these medications
- ∞ EXALGO contains hydromorphone, and should be taken only as directed.
- ∞ EXALGO must be swallowed whole. The extended release tablets may release all their contents at once if broken, chewed, crushed, or dissolved resulting in risk of fatal overdose of hydromorphone.
- ∞ Do not to take another dose of EXALGO within 24 hours.
- ∞ Never to change the dose of EXALGO without first consulting their healthcare provider.
- ∞ Keep EXALGO tablets in a secure place out of the reach of children. Accidental consumption of EXALGO, especially in children, can result in a fatal overdose of hydromorphone.
- ∞ EXALGO must not be given to anyone other than the individual for whom it was prescribed. Instruct patients against use by individuals other than the patient for whom it was prescribed, as such inappropriate use may have severe medical consequences, including death.

2.2 Bottle Label

The bottle label will include a statement instructing the authorized dispenser that EXALGO is for opioid-tolerant patients only and to provide a copy of the Medication Guide with each EXALGO prescription. The bottle label also contains the important reminder information for pharmacists that EXALGO tablets should be swallowed whole and tablets should not be broken, crushed, or chewed (**Figure 6**).

EXALGO® (hydromorphone HCl) Extended-Release Tablets, CII
Risk Mitigation Strategy Overview**Mallinckrodt Inc.**

Figure 6: EXALGO Bottle Label (32 mg tablet strength)

**2.3 Medication Guide**

The primary communication to patients will come from the EXALGO Medication Guide. The Medication Guide contains information on the risks of EXALGO as well as information on safe use. The information included in the Medication Guide is presented in easy-to-understand language that is appropriate for patients. See **Figure 7** for an example of the information contained in the Medication Guide.

Figure 7: Medication Guide Important Information (selected)

□

- ∞ Keep EXALGO in a safe place away from children. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes EXALGO, get emergency help right away, even if the child is not having any side effects.
- ∞ Do not take EXALGO unless you are already regularly using opioid pain medicines around-the-clock and your body is used to taking these medicines. This means you are opioid tolerant.
- ∞ Take EXALGO exactly as prescribed by your healthcare provider. Do not take more than your prescribed daily dose. It is important that you do not take another dose of EXALGO within 24 hours.
- ∞ Swallow the EXALGO tablet whole. Do not break, chew, crush, or dissolve EXALGO before swallowing, or inject the contents. You could receive the full daily dose of medicine too fast. This is very dangerous. It may cause you to have trouble breathing, and lead to death. If you cannot swallow EXALGO whole, tell your healthcare provider. You will need a different pain medicine.
- ∞ EXALGO is not for use to treat pain that you only have once in a while ("as-needed").
- ∞ EXALGO is not for use for short-term pain relief from injuries or surgery.
- ∞ It is important for you to stay under the care of your healthcare provider while taking EXALGO.

A Medication Guide will be dispensed with each EXALGO prescription. To ensure compliance with Title 21 of the Code of Federal Regulations (21 CFR) §208.24, Mallinckrodt will ensure that the Medication Guide is available for distribution to patients receiving a prescription of EXALGO by providing sufficient numbers of the Medication Guide to distributors and authorized dispensers.

- ∞ Medication Guides will be included in the primary and secondary packaging of the commercial product
- ∞ One (1) Medication Guide will be affixed (spot glued) to each bottle of EXALGO
- ∞ Additional Medication Guides (48) will be provided with each carton containing 12 bottles of EXALGO; partial cases will include four (4) additional Medication Guides per bottle
- ∞ The Medication Guide also will be available through the product website (www.exalgo.com), the EXALGO REMS website (www.exalgorems.com), and through the Mallinckrodt toll-free Product Monitoring Department number at 1-800-778-7898
- ∞ The Medication Guide also will be distributed with the EXALGO REMS Healthcare Professional Education Program Kit as part of the prescribing education program

2.3.1 Medication Guide Tear Pads

Upon request, Mallinckrodt will provide Medication Guide Tear Pads to pharmacies that dispense EXALGO. The Medication Guide Tear Pads will be available through the product website (www.exalgo.com), the EXALGO REMS website (www.exalgorems.com), and through the Mallinckrodt toll-free Product Monitoring Department number at 1-800-778-7898.

2.4 Education for Healthcare Professionals

Mallinckrodt will ensure that HCPs who prescribe EXALGO will receive training on the risks, appropriate prescribing, and safe use of EXALGO. Mallinckrodt will ensure that training will be provided to HCPs who prescribe EXALGO. To become trained, each prescriber will be provided with the materials in the EXALGO REMS Healthcare Professional Education Program Kit (see below).

The Healthcare Professional Education Program Kit includes the following content:

- ∞ Proper patient selection
- ∞ Appropriate EXALGO dosing and administration
- ∞ General opioid use, including information about opioid abuse and how to identify patients who are at risk for abuse and addiction
- ∞ The risks of abuse, misuse, overdose, and addiction from exposure to opioids, including EXALGO
- ∞ The risks of EXALGO, including:
 - The risk of overdose caused by exposure to an essentially immediate-release form of hydromorphone due to broken, chewed, crushed, or dissolved EXALGO

- The risk of addiction from exposure to EXALGO
- The risk of overdose with use of EXALGO
- ∞ Information to counsel patients on the need to store opioid analgesics safely out of the reach of children and household acquaintances
- ∞ The importance of providing each patient a Medication Guide with each prescription and instructing the patient to read it

Mallinckrodt will ensure that within 60 days of approval of the updated Full Prescribing Information and EXALGO REMS, a Dear Healthcare Professional Introductory Letter will be mailed to all EXALGO prescribers (defined as all who are known to have written an EXALGO prescription) and to prescribers most experienced in treating chronic pain with opioid agonists. This letter is designed to convey and reinforce the risks of abuse, misuse, overdose, and addiction of EXALGO as well as the need to complete the EXALGO REMS Education Program. This letter will also be available on the www.exalgorems.com website. The EXALGO Healthcare Professional Education Program Kit will be included in this mailing.

Additional printed educational material will be made available through field-force distribution and Mallinckrodt's toll-free Product Monitoring Department number at 1-800-778-7898. The educational material will be available for download at www.exalgorems.com.

Mallinckrodt will maintain a list of all prescribers who have completed the EXALGO REMS Healthcare Professional Education Program. Prescribers will be re-educated, including review of the educational materials and completion of the Education Confirmation Form, every 2 years or following substantial changes to the EXALGO REMS. Substantial changes may include changes in the EXALGO Full Prescribing Information, Medication Guide, or EXALGO REMS that require substantial modification to the educational materials.

2.4.1 Healthcare Professional Education Program Kit

The Healthcare Professional Education Program Kit contains all of the information necessary to complete the Healthcare Professional Education Program (**Figure 8**). It will consist of the following educational materials:

- ∞ Dear Healthcare Professional Introductory Letter
- ∞ Prescribing Brochure
- ∞ Education Confirmation Form (ECF)
- ∞ Full Prescribing Information
- ∞ Medication Guide
- ∞ Safe Use and Handling Guide

Figure 8: Healthcare Professional Education Program Kit



2.4.1.1 Dear Healthcare Professional Introductory Letter

Mallinckrodt will send a Dear Healthcare Professional Introductory Letter along with the EXALGO REMS Healthcare Professional Education Program Kit by direct mail to all prescribers who have prescribed EXALGO and to HCPs most likely to prescribe EXALGO. This letter is designed to convey and reinforce the potential risks associated with the use of EXALGO. This letter will also reinforce the appropriate use of EXALGO and emphasize the importance of prescriber review of the EXALGO educational material.

2.4.1.2 Prescribing Brochure

The Prescribing Brochure contains the essential information for HCPs who prescribe EXALGO. See **Figure 9** for sample pages of the Prescribing Brochure.

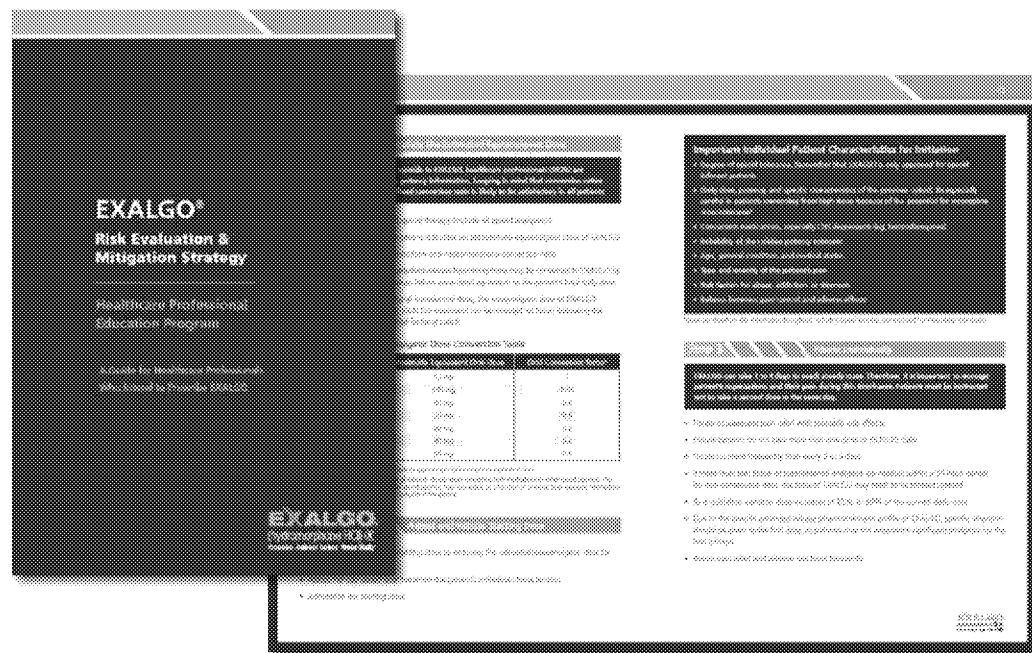
The Prescribing Brochure includes the following content:

- ∞ Proper patient selection
- ∞ Appropriate EXALGO dosing and administration
- ∞ General opioid use, including information about opioid abuse and how to identify patients who are at risk for abuse and addiction
- ∞ The risks of abuse, misuse, overdose, and addiction from exposure to opioids, including EXALGO
- ∞ The risks of EXALGO, including:
 - The risk of overdose caused by exposure to an essentially immediate-release form of hydromorphone due to broken, chewed, crushed, or dissolved EXALGO
 - The risk of addiction from exposure to EXALGO
 - The risk of overdose with use of EXALGO
- ∞ Information to counsel patients on the need to store opioid analgesics safely out of the reach of children and household acquaintances
- ∞ The importance of providing each patient a Medication Guide with each prescription and instructing the patient to read it

EXALGO® (hydromorphone HCl) Extended-Release Tablets, CII
Risk Mitigation Strategy Overview

Mallinckrodt Inc.

Figure 9: Prescribing Brochure





The Prescribing Brochure will be disseminated with the Dear Healthcare Professional Introductory Letters. In addition, it will be available for distribution by the field force and for download from the www.exalgorems.com website.

EXALGO® (hydromorphone HCl) Extended-Release Tablets, CII
Risk Mitigation Strategy Overview**Mallinckrodt Inc.****2.4.1.3 Education Confirmation Form (ECF)**

The ECF is used to confirm the completion of the REMS education and contains questions intended to serve as a reminder of the most essential safety information. This form is currently called the EXALGO Essential Information Form. This form will be modified to include the 32 mg tablet and associated risks. The form also can be completed via print or electronically at www.exalgorems.com and can be submitted electronically, via fax, or via e-mail. The content for the ECF is presented below (**Figure 10**). The content has been revised to support the approval of the 32 mg tablet strength.

Figure 10: Education Confirmation Form

Education Confirmation Form <small>The purpose of this form is to confirm that you have read and understand the EXALGO® REMS education materials. Completion of this form does not affect your ability to prescribe EXALGO.</small>		 EXALGO <small>hydromorphone HCl CII</small> <small>Extended-Release Tablet</small>
Important Reminders About the Appropriate Prescribing and Safe Use of EXALGO		
<input checked="" type="checkbox"/> The primary REMS-related risks of EXALGO include: <div style="display: flex; justify-content: space-around; font-size: small;"> • Abuse • Misuse • Overdose • Addiction </div>		
<input checked="" type="checkbox"/> EXALGO should be prescribed only for the following condition: <small>Moderate to severe chronic pain in opioid-tolerant patients requiring around-the-clock opioid analgesia for an extended period of time</small>		
<input checked="" type="checkbox"/> The EXALGO Full Prescribing Information defines opioid tolerance as patients taking one of the following for a week or longer: <div style="display: flex; justify-content: space-around; font-size: small;"> • At least 60 mg oral morphine/day • At least 8 mg oral hydromorphone/day </div> <div style="display: flex; justify-content: space-around; font-size: small;"> • At least 30 mg oral oxycodone/day • At least 15 mg transdermal fentanyl/hour </div> <div style="display: flex; justify-content: space-around; font-size: small;"> • At least 25 mg oral oxycodone/day </div>		
<input checked="" type="checkbox"/> The only safe way to take EXALGO is by swallowing the tablet whole or intact. EXALGO should never be broken, split, chewed, crushed, or dissolved.		
<input checked="" type="checkbox"/> Patients should be counseled to read the EXALGO Medication Guide that they receive with every prescription, as important information may have changed.		
I have read and understand the EXALGO REMS education materials.		
Signature _____ Date _____		
Prescriber Name, Credentials _____		
DEA Registration Number _____ Specialty _____		
Address _____		
City _____ State _____ Zip _____		
Office Phone _____ Office Fax _____		
E-mail _____		
How do you want to be informed of the receipt of this form? Fax <input type="checkbox"/> E-mail <input type="checkbox"/>		
Please return the completed form • via e-mail to exalgorems@covidien.com • via fax to 1.888.423.3511		For additional educational information, go to www.exalgorems.com or call 1.888.9EXALGO (1.888.939.2546).
<small>Please see full Prescribing Information, including BOXED WARNING. © 2012/2013 Covidien with copyright. All rights reserved. All other copyright(s) are the property of their respective owners. EXALGO is a registered trademark of Covidien Corporation. All other trademarks are the property of their respective owners. 2012 Printed in USA.</small>		
Mallinckrodt		

2.4.1.4 Prescribing Information/Medication Guide

The Full Prescribing Information, including Medication Guide, will be provided in the Healthcare Professional Education Program Kit. The Prescribing Information and Medication Guide are also attached to the Prescribing Brochure.

2.4.1.5 Safe Use and Handling Guide

The Safe Use and Handling Guide is an educational resource for prescribers to educate patients on the risks, safe use, storage, and disposal of EXALGO. Prescribers can obtain additional Safe Use and Handling Guides from the www.exalgorems.com website and the Mallinckrodt toll-free Product Monitoring Department number at 1-800-778-7898.

The Safe Use and Handling Guide includes the following content:

- ∞ The risks of EXALGO
- ∞ How to take EXALGO properly, including:
 - Adherence to dosing regimen
 - Risks of breaking, chewing, and crushing
 - Symptoms of overdose
- ∞ Reporting of adverse events
- ∞ Concomitant use of other CNS depressants, alcohol, or illegal drugs
- ∞ Discontinuation of EXALGO
- ∞ Risks associated with sharing
- ∞ Proper storage in the household
- ∞ Avoiding unsafe exposure by preventing theft and ensuring proper disposal
- ∞ Purpose and content of a Patient-Provider Agreement

2.4.2 Online Resources

2.4.2.1 EXALGO REMS Website (www.exalgorems.com)

The EXALGO REMS website (www.exalgorems.com) contains information about the EXALGO REMS program and serves as one method by which prescribers can become educated on the risks, appropriate prescribing, and safe use of EXALGO (**Figure 11**). The website also contains the appropriate forms and resources to facilitate proper prescribing and safe use. The website is referenced in the EXALGO REMS–related materials provided to prescribers, pharmacists, and patients. It also serves as a resource for accessing all EXALGO REMS educational materials, including the Prescribing Brochure and ECF.

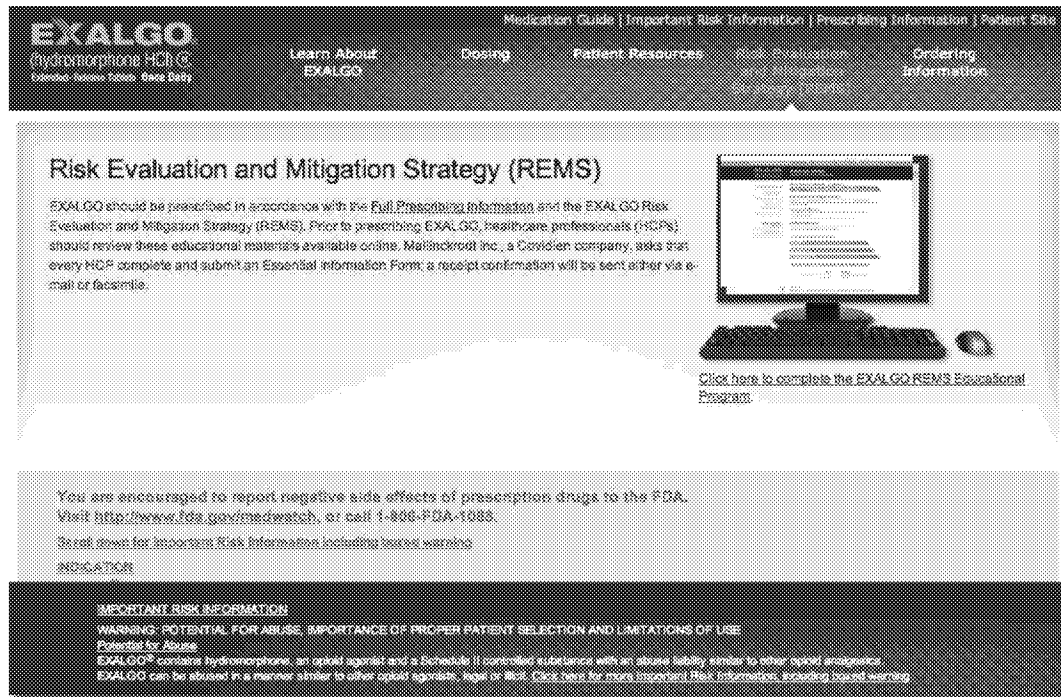
Figure 11: www.exalgorems.com Website



2.4.2.2 EXALGO Product Website (www.exalgo.com)

The EXALGO website (www.exalgo.com) contains product information as well as information and resources about appropriate use. This website provides a direct link to the www.exalgo.rems.com website. This website also contains supplemental resources and support tools to facilitate appropriate prescribing and safe use, as described below (**Figure 12**).

Figure 12: www.exalgo.com Website



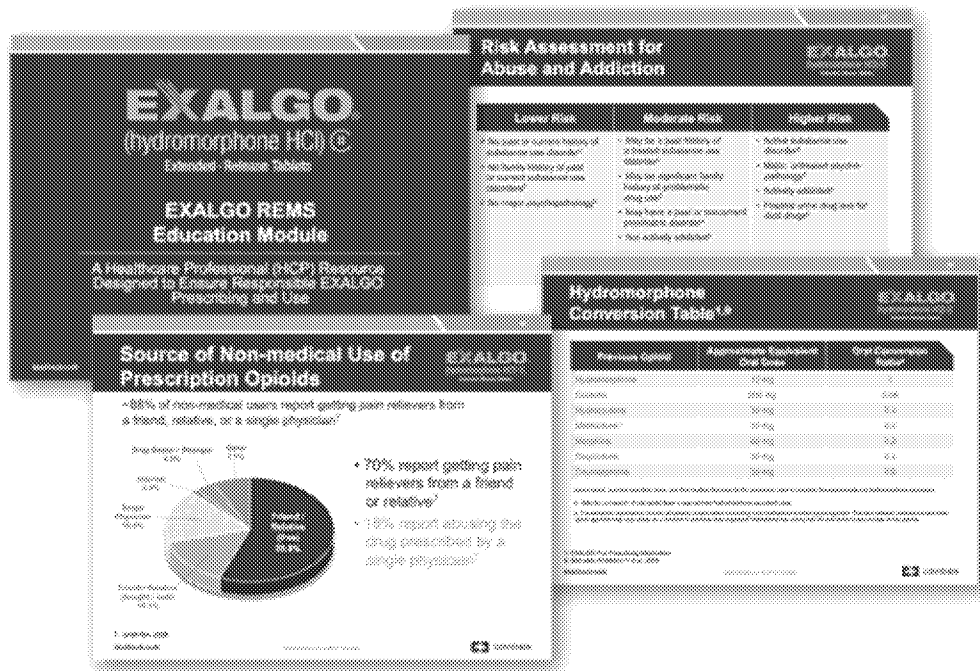
3. EXALGO REMS EDUCATION AND OUTREACH

Additional EXALGO REMS risk mitigation tools and activities will provide additional education and outreach tools and activities for EXALGO REMS education material. Highlights are provided here. All content will be updated with the approved EXALGO REMS information. See Appendix B for a complete list of risk mitigation tools and activities.

3.1 EXALGO REMS Education Module

The EXALGO REMS Education Module contains all of the information in the EXALGO REMS Prescribing Brochure and is used to educate potential EXALGO prescribers and allied HCPs on EXALGO risks, appropriate prescribing, and safe use at live education and outreach activities (e.g., webinars, live training). See **Figure 13** for sample slides.

Figure 13: EXALGO REMS Education Module



3.2 EXALGO REMS Education Videos

The EXALGO REMS Overview Video is used to introduce the EXALGO REMS program, EXALGO risks, and the EXALGO REMS education requirements and procedures to potential EXALGO prescribers and allied HCPs at live education and outreach activities (e.g., webinars, live training, congress booths) (**Figure 14**). The EXALGO REMS Education Video contains experts in appropriate opioid prescribing (Steven Passik, PhD; Jeffrey Gudin, MD) presenting the EXALGO REMS Education Module and is used to educate potential EXALGO prescribers on EXALGO risks, appropriate prescribing, and safe use at live education and outreach activities (e.g., webinars, live training) (**Figure 15**).

EXALGO® (hydromorphone HCl) Extended-Release Tablets, CII
Risk Mitigation Strategy Overview

Mallinckrodt Inc.

Figure 14: EXALGO REMS Overview Video (current REMS depicted)

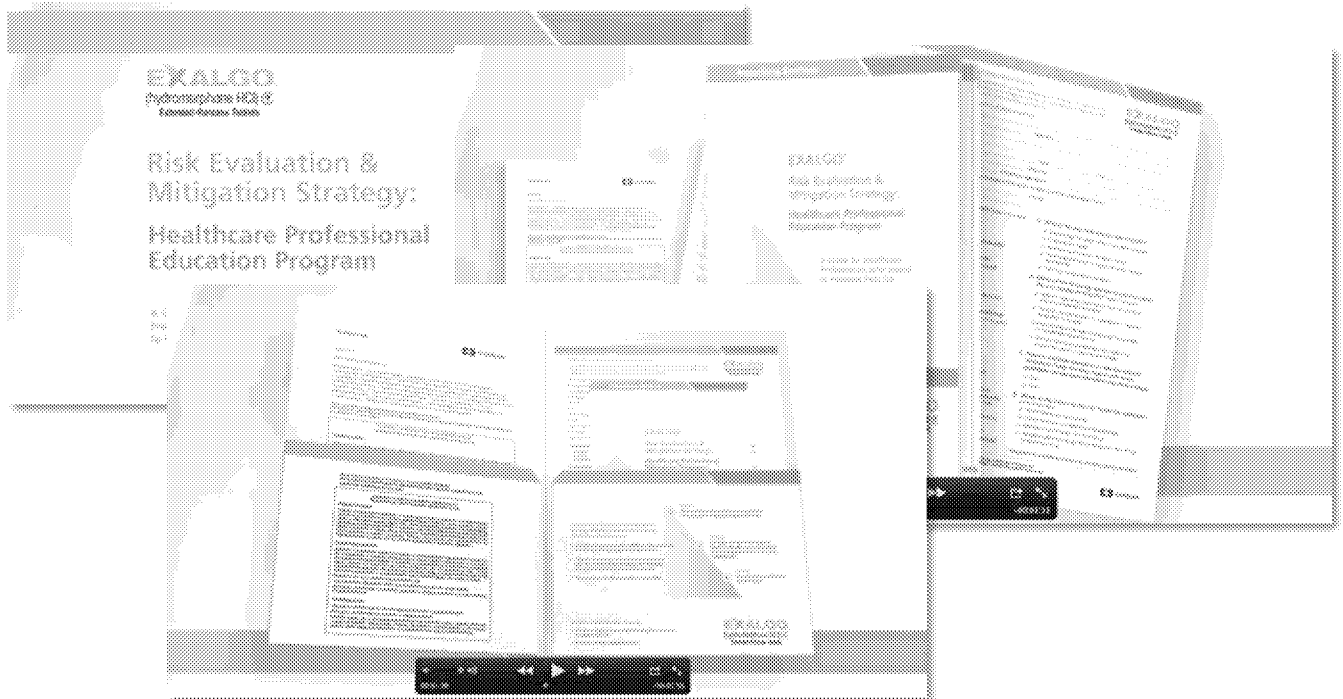
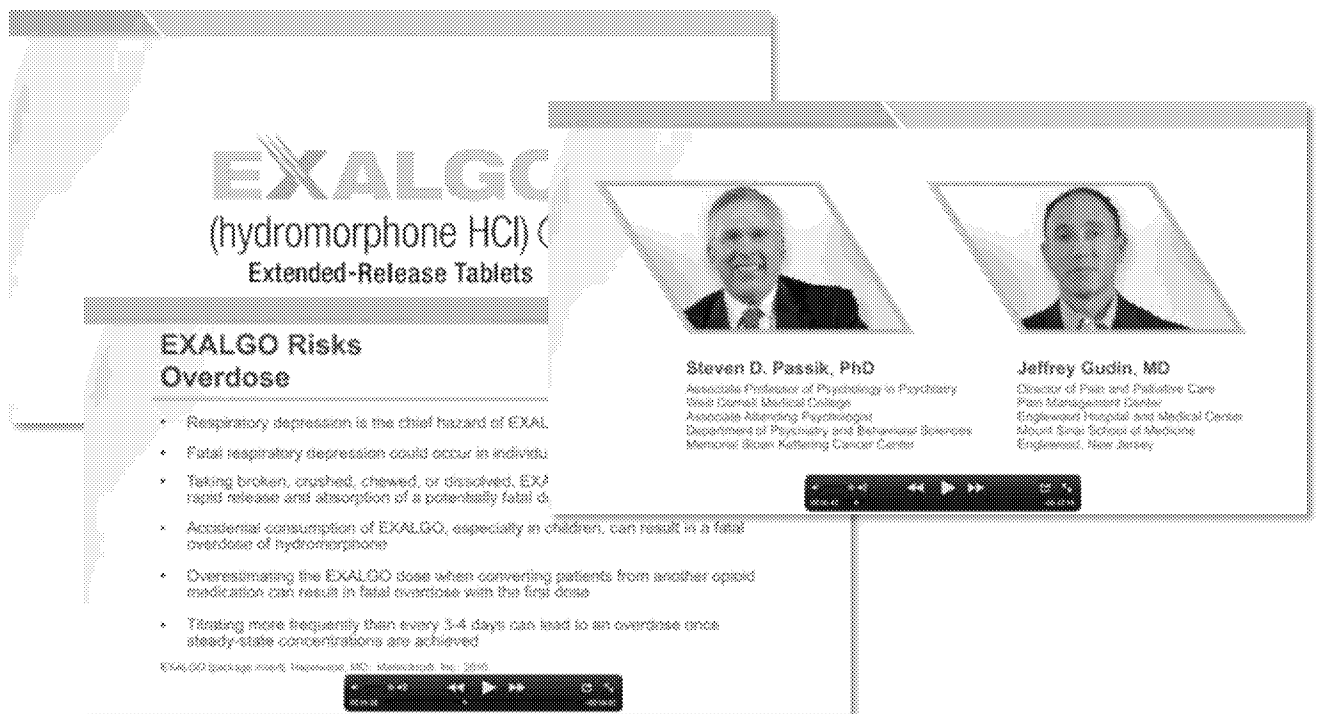


Figure 15: EXALGO REMS Education Video (current REMS depicted)



3.3 EXALGO REMS Education Webinars

The EXALGO REMS Education Webinars are live education events used to educate potential EXALGO prescribers and allied HCPs on EXALGO risks, appropriate prescribing, and safe use. Faculty for this education series are experts in pain medicine and addiction and trained on EXALGO prescribing and the EXALGO REMS education material.

3.4 Pharmacist Communication Plan

Mallinckrodt will ensure that pharmacies that dispense EXALGO receive the REMS education material on the risks, appropriate prescribing, and safe use of EXALGO. Mallinckrodt will ensure that within 60 days of approval of the updated Full Prescribing Information and EXALGO REMS, a Dear Pharmacist Introductory Letter will be mailed to all pharmacies that dispense EXALGO (defined as all pharmacies known to have stocked and/or dispensed EXALGO). This letter is designed to convey and reinforce the risks of abuse, misuse, overdose, and addiction of EXALGO. The letter will also reinforce the need to dispense a Medication Guide with every prescription and counsel the patient on safe use, as well as the requirement that EXALGO is only for opioid-tolerant patients. The pharmacist mailing will also include the EXALGO REMS Prescribing Brochure, a copy of the EXALGO Dispensing Checklist as well as an example of and means to order the EXALGO Medication Tear Pad.

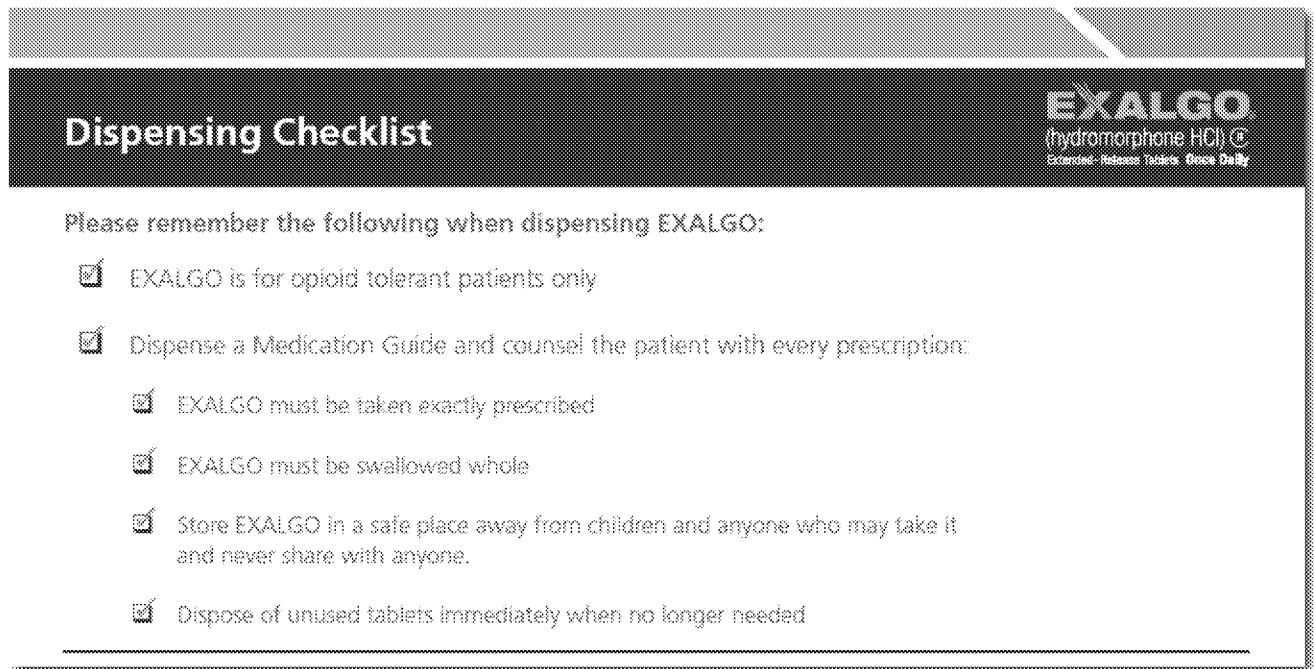
3.5 Medication Guide Tear Pads

Mallinckrodt will provide Medication Guide Tear Pads to pharmacies that dispense EXALGO. The Medication Guide Tear Pads also will be available through the product website (www.exalgo.com), the EXALGO REMS website (www.exalgorems.com), and through the Mallinckrodt toll-free Product Monitoring Department number at 1-800-778-7898.

3.6 EXALGO Dispensing Checklist

The EXALGO Dispensing Checklist will be used to remind pharmacists of the risks of abuse, misuse, overdose, and addiction of EXALGO. The checklist will also remind the pharmacist of the need to dispense a Medication Guide with every prescription, the need to counsel patients and caregivers on safe use (especially the need to swallow EXALGO whole and not to break, chew, crush, or dissolve the tablet), and the requirement that EXALGO is only for opioid-tolerant patients. The content of the EXALGO Dispensing Checklist is shown in **Figure 16** (Indication and important risk information are also included on the form.)

Figure 16: EXALGO Dispensing Checklist



Dispensing Checklist

EXALGO[®]
(hydromorphone HCl) CII
Extended-Release Tablets Once Daily

Please remember the following when dispensing EXALGO:

- ☒ EXALGO is for opioid tolerant patients only
- ☒ Dispense a Medication Guide and counsel the patient with every prescription:
 - ☒ EXALGO must be taken exactly prescribed
 - ☒ EXALGO must be swallowed whole
 - ☒ Store EXALGO in a safe place away from children and anyone who may take it and never share with anyone.
 - ☒ Dispose of unused tablets immediately when no longer needed

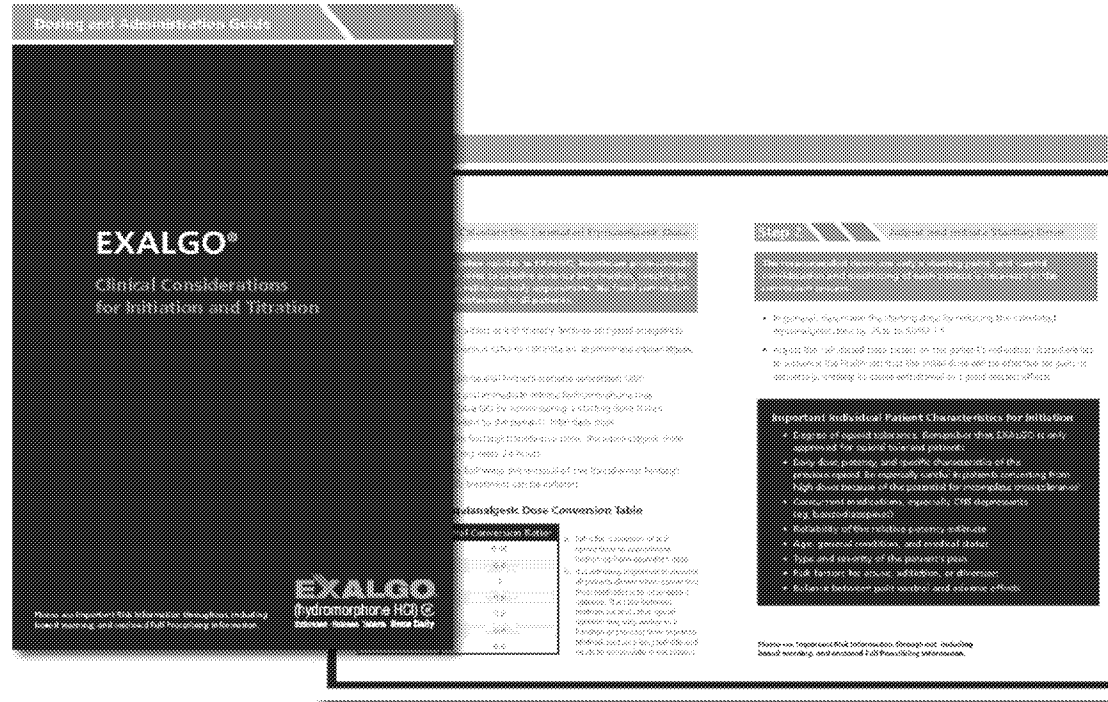
4. EXALGO-SPECIFIC RISK MITIGATION TOOLS AND ACTIVITIES

Additional EXALGO-specific risk mitigation tools and activities provide HCPs with information on EXALGO risks, appropriate prescribing (e.g., especially proper dosing and administration), and safe use. Patient tools provide patients with information on EXALGO risks and safe use.

4.1 EXALGO Dosing and Administration Guide

The EXALGO Dosing and Administration Guide is an HCP brochure intended to supplement the Full Prescribing Information and the EXALGO REMS Prescribing Brochure on proper dosing and administration of EXALGO. This brochure is provided by the sales force (**Figure 17**).

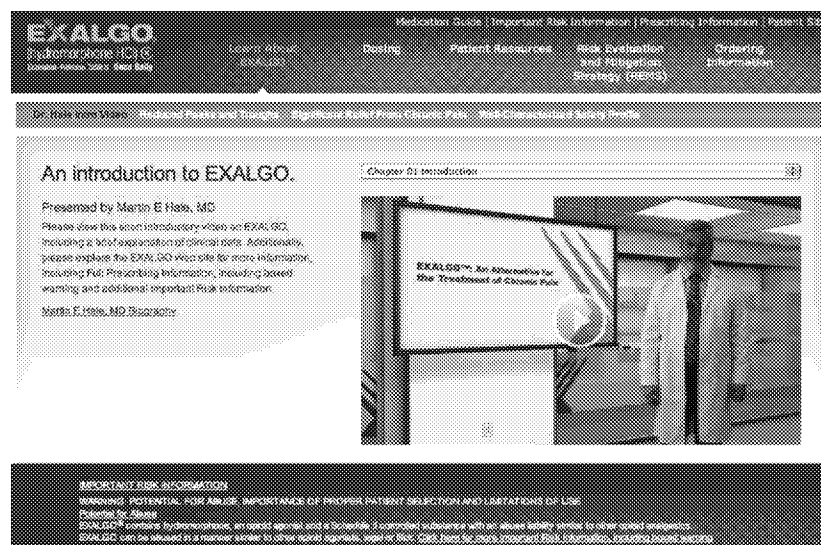
Figure 17: EXALGO Dosing and Administration Guide



4.2 Introduction to EXALGO Healthcare Professional Video

The www.exalgo.com website contains a video in which an expert in pain medicine and EXALGO presents key information for EXALGO, including the prescribing information. This video is intended to educate HCPs on core safety information, including EXALGO risks and appropriate prescribing, such as patient selection and dosing and administration (**Figure 18**).

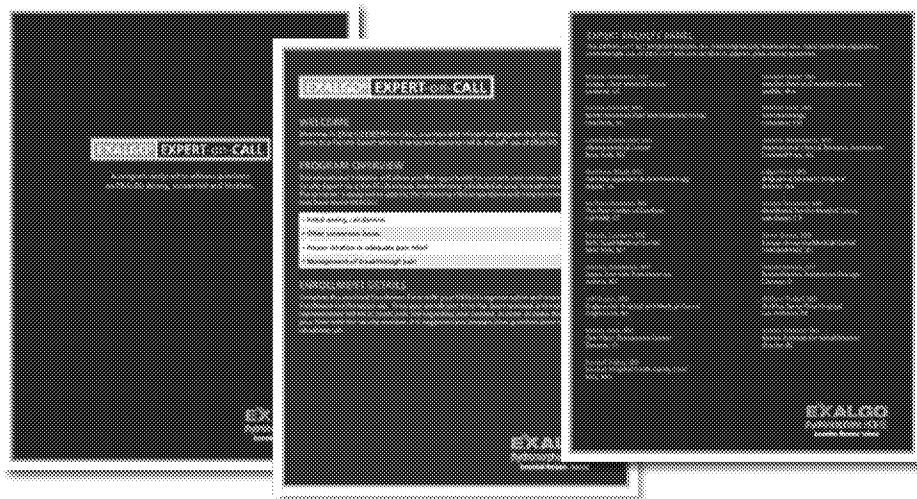
Figure 18: Introduction to EXALGO Healthcare Professional Video



4.3 EXALGO Expert-on-Call Program

The Expert-on-Call program provides HCPs the opportunity to get answers to questions about EXALGO prescribing and use from experts in opioid prescribing and safe use who have also been trained on the EXALGO REMS educational content and EXALGO prescribing. The program, faculty, and schedule will be communicated by the field force (**Figure 19**).

Figure 19: EXALGO Expert-on-Call Program



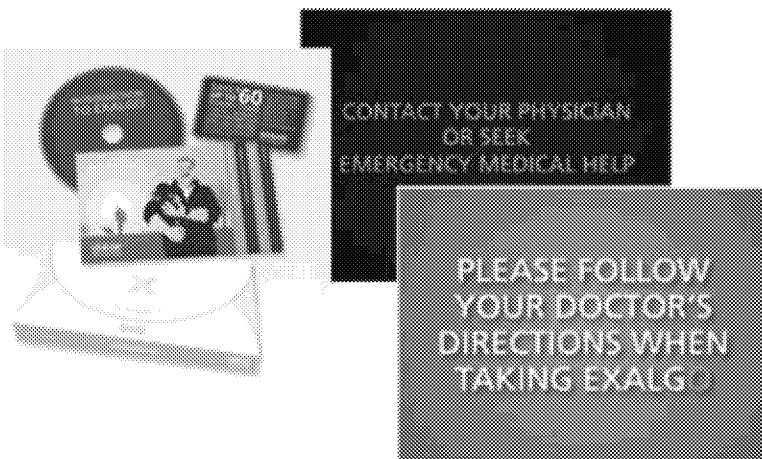
4.4 EXALGO Promotional Speakers' Bureau

All EXALGO promotional speakers are trained on the EXALGO REMS education content and frequently asked questions on responsible EXALGO prescribing and use. These individuals, who speak at hundreds of promotional programs per year, encourage prescribers to complete the EXALGO REMS education program.

4.5 Introduction to EXALGO Patient Video

The introduction to EXALGO patient video is provided to all patients upon their initial prescription of EXALGO. This video educates patients on the risks and safe use of EXALGO, including proper use (e.g., EXALGO must be swallowed whole) and storage and disposal (**Figure 20**).

Figure 20: Introduction to EXALGO Patient Video



5. GENERAL OPIOID RISK MITIGATION TOOLS AND ACTIVITIES

Additional general opioid risk mitigation tools and activities will be provided through the C.A.R.E.S. Alliance program, which provides education and resources to HCPs and patients about opioid risks, responsible prescribing, and safe use. Mallinckrodt also provides support for local outreach programs and independent medical education on appropriate prescribing and safe use of prescription opioid analgesics. The C.A.R.E.S. Alliance catalog, which provides information on all tools and activities, will be included with all EXALGO mailings. Highlights of the C.A.R.E.S. Alliance program are presented here. See Appendix D for a complete list of risk mitigation tools and activities.

5.1 The C.A.R.E.S. Alliance Education, Resources, and Support Program

The C.A.R.E.S. Alliance provides educational programs and resources to support responsible prescribing and safe use of opioid analgesics. The C.A.R.E.S. Alliance also facilitates collaboration among stakeholders involved in the safe use of prescription opioid analgesics (e.g., HCPs and patients), through the development and distribution of innovative educational resources.

To support efforts to ensure the safe prescribing and use of opioid pain medications, the C.A.R.E.S. Alliance has developed and assembled an array of tools to be used by prescribers, patients, and pharmacists. Some tools can help HCPs predict a patient's risk of abuse or addiction prior to treatment, whereas others can help identify aberrant behaviors once a patient has started treatment with an opioid pain medication. In addition, HCPs can find clinical guidelines and best practices developed by leaders in the field of pain management to facilitate appropriate prescribing in order to reduce the serious risks associated with opioids (i.e., overdose, misuse, abuse, and addiction) as well as resources for patients to help them understand their medication,

use their medication properly, and better communicate with their HCP. A number of tools are also available to help pharmacists responsibly dispense opioid pain medication to properly screened and counseled patients.

5.1.1 Opioid Clinical Management Guide and Checklist

The Opioid Clinical Management Guide is a resource for responsible opioid prescribing and use that can help HCPs improve patient outcomes by enhancing knowledge of the potential risks, responsible prescribing, and safe use of opioid pain medications. This brochure summarizes best practices for chronic opioid therapy in chronic non-cancer pain endorsed by the American Pain Society and American Academy of Pain Medicine (Chou et al, 2009). The guide provides important information on misuse, abuse, addiction, overdose, adverse events, patient selection, monitoring, counseling, treatment initiation, and discontinuation (**Figure 21**). A convenient, one-page checklist is also provided to assist HCPs in optimizing the effectiveness of opioid analgesics and improving patient outcomes (**Figure 22**).

Figure 21: Opioid Clinical Management Guide

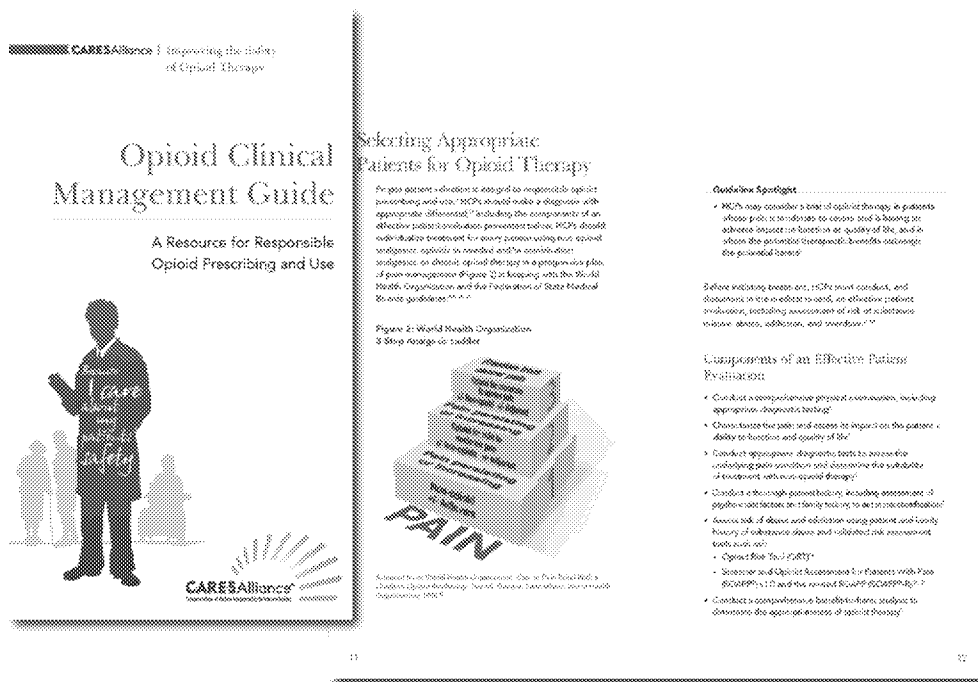
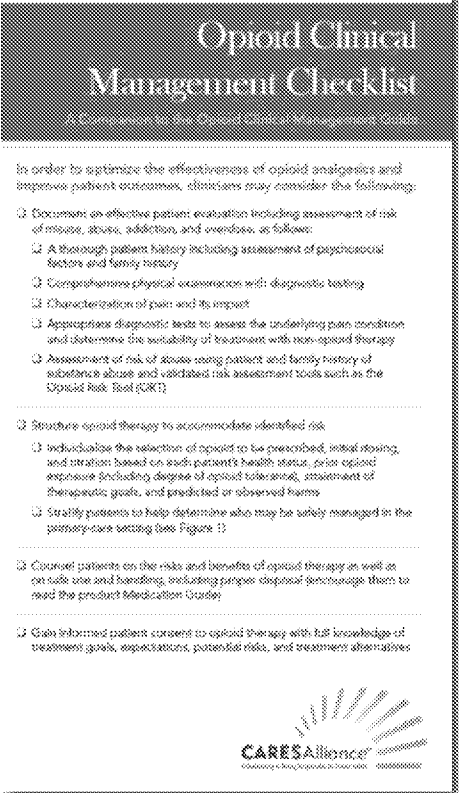


Figure 22: Opioid Clinical Management Checklist



Opioid Clinical Management Checklist
A Companion to the Opioid Risk Management Guide

In order to optimize the effectiveness of opioid analgesics and improve patient outcomes, clinicians may consider the following:

- Document an effective patient evaluation including assessment of risk of misuse, abuse, addiction, and overdose, as follows:
 - A thorough patient history including assessment of psychosocial factors and family history
 - Comprehensive physical examination with diagnostic testing
 - Characterization of pain and its impact
 - Appropriate diagnostic tests to assess the underlying pain condition and determine the suitability of treatment with non-opioid therapy
 - Assessment of risk of abuse using patient and family history of substance abuse and validated risk assessment tools such as the Opioid Risk Tool (ORT)
- Structure opioid therapy to accommodate identified risk:
 - Individualize the selection of opioid to be prescribed, initial dosing, and titration based on each patient's health status, prior opioid exposure (including degree of opioid tolerance), assessment of therapeutic goals, and predicted or observed harms
 - Stratify patients to help determine who may be safely managed in the primary-care setting (see Figure 1)
- Counsel patients on the risks and benefits of opioid therapy as well as on safe use and handling, including proper disposal techniques (them to read the product Medication Guide)
- Gain informed patient consent to opioid therapy with full knowledge of treatment goals, expectations, potential risks, and treatment alternatives

CARE Alliance
www.carealliance.org

Figure 1: Risk Stratification

Lowest Risk Primary Care Patients	Moderate Risk Primary Care Patients Management Required	Highest Risk Non-Primary Care Patients
ORT Score: 0-5	ORT Score: 6-7	ORT Score: 8+
<ul style="list-style-type: none"> No past or current substance use disorders No family history of substance use disorders No major or untreated psychopathology 	<ul style="list-style-type: none"> May have a history of substance use disorders May have a family history of problematic drug use May have past or current psychopathology Not actively addicted 	<ul style="list-style-type: none"> Active substance use disorders Major, untreated psychopathology Actively addicted

Adapted from Dunlop, Pitt, Anand, 2009 and Miller and Wilkins 2009

- Define responsibilities and expectations using a written opioid use agreement
- Monitor patients periodically and as warranted
 - Document at all visits:
 - Analgasia (sustained efficacy) including use of validated scales
 - Activities of daily living and progress toward achieving therapeutic goals
 - Adverse events
 - Adherent drug-related behaviors + address if present
 - In addition to patient self-report, other monitoring tools to verify adherence to the therapeutic plan include urine drug screens and pill counts
- Manage patients who are at high risk for or who are currently engaging in aberrant drug-related behaviors in accordance with current guidelines
- Collaborate with or refer patients to specialists when needed

For additional information and resources, or assistance in prescribing of opioids please go to www.carealliance.org

1. Dunlop D, Pitt R, Anand D. Opioid prescribing: A practical approach to the best practice. *BMJ Best Practice*. 2009;2009:100114.
2. Wilkins S, Pitt R, Anand D. Opioid prescribing: A practical approach to the best practice. *BMJ Best Practice*. 2009;2009:100114.
3. Dunlop D, Pitt R, Anand D. Opioid prescribing: A practical approach to the best practice. *BMJ Best Practice*. 2009;2009:100114.

Sponsored by **CARE Alliance** was created to help patients, healthcare professionals, and the pharmaceutical industry work together to improve patient safety.

COVIDIEN

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Euronext:MTI
www.covidien.com

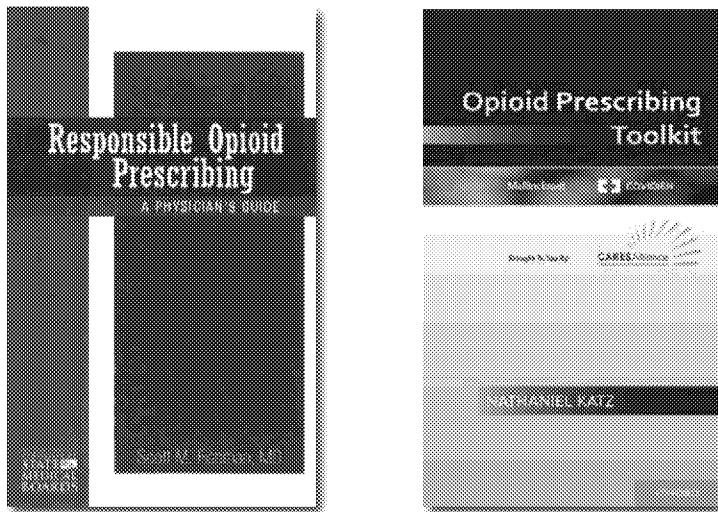
5.1.2 Opioid Clinical Management Education and Outreach Program

The Opioid Clinical Management Education and Outreach Program educates prescribers on the risks and appropriate prescribing and use of opioid analgesics. The outreach program communicates the availability of and facilitates the dissemination of the C.A.R.E.S. Alliance education and support tools. The program contains print and video content, delivered through congresses and online activities.

5.1.3 Responsible Opioid Prescribing Books

Two books are available to educate EXALGO prescribers on appropriate prescribing. *Responsible Opioid Prescribing: A Physician's Guide*, authored by Scott M. Fishman, MD, provides strategies to aid in the use of prescription opioids for chronic pain and to help reduce the risk of addiction, abuse, and diversion when prescribing opioid pain medication (Fishman, 2007). It provides concise steps based on the Federation of State Medical Board's *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (**Figure 23**). The *Opioid Prescribing Toolkit*, developed by Nathaniel Katz, MD, is a workbook and accompanying CD-ROM that provides a comprehensive array of user-friendly tools to help HCPs safely and effectively prescribe opioid pain medication to patients with chronic pain (**Figure 23**).

Figure 23: Responsible Opioid Prescribing Books



5.1.4 Healthcare Professional Ask-an-Expert Video Series

This video series features experts in the responsible prescribing of opioid analgesics for patients with chronic pain. Jeffrey Gudin, MD, discusses the importance of prescribing opioids responsibly, including appropriate patient selection, dosing, and counseling to ensure safe use. In addition, Steven D. Passik, PhD, and Lynn Webster, MD, focus their discussions on the importance of a thorough risk assessment for aberrant drug-related behaviors in every patient being considered for opioid therapy. The physicians discuss the elements of risk stratification, including use of validated risk stratification tools, prescription monitoring programs, and consultation with referring physicians and pharmacies to ensure appropriate use (**Figure 24**).

Figure 24: Ask-an-Expert Video Series



5.1.5 Literature Reprint Carriers

Reprint carriers have been developed that focus on evidence-based treatment guidelines, urine drug testing, and appropriate patient selection. The American Pain Society/American Academy of Pain Medicine (APS/AAPM) Opioid Treatment Guidelines Reprint Carrier is an educational tool that provides current, evidence-based recommendations on the use of opioid medications to treat chronic noncancer pain (Chou et al, 2009). Developed by a multidisciplinary expert panel, this resource includes recommendations on all aspects of responsible opioid prescribing patient evaluation and selection, structuring of opioid therapy to accommodate risk, appropriate initiation and titration, and regular and comprehensive patient monitoring (**Figure 25**). The Urine Drug Screening (UDS) Reprint Carrier is an educational tool for prescribers that details the limitations of UDS and assessment of results using both objective and clinical information (Moeller et al, 2008). This document contains information on screening for commonly abused drugs, including opioids, alcohol, amphetamines, benzodiazepines, marijuana, and cocaine (**Figure 25**). The Universal Precautions in Pain Medicine Reprint Carrier is an educational tool for prescribers consisting of articles that describe a Universal Precautions approach to the assessment, risk stratification, and ongoing management of patients with chronic pain, including the inherited patient (**Figure 25**) (Gourlay et al, 2005; Gourlay and Heit, 2009). See Appendix D for additional details on reprint carriers.

Figure 25: Reprint Carriers

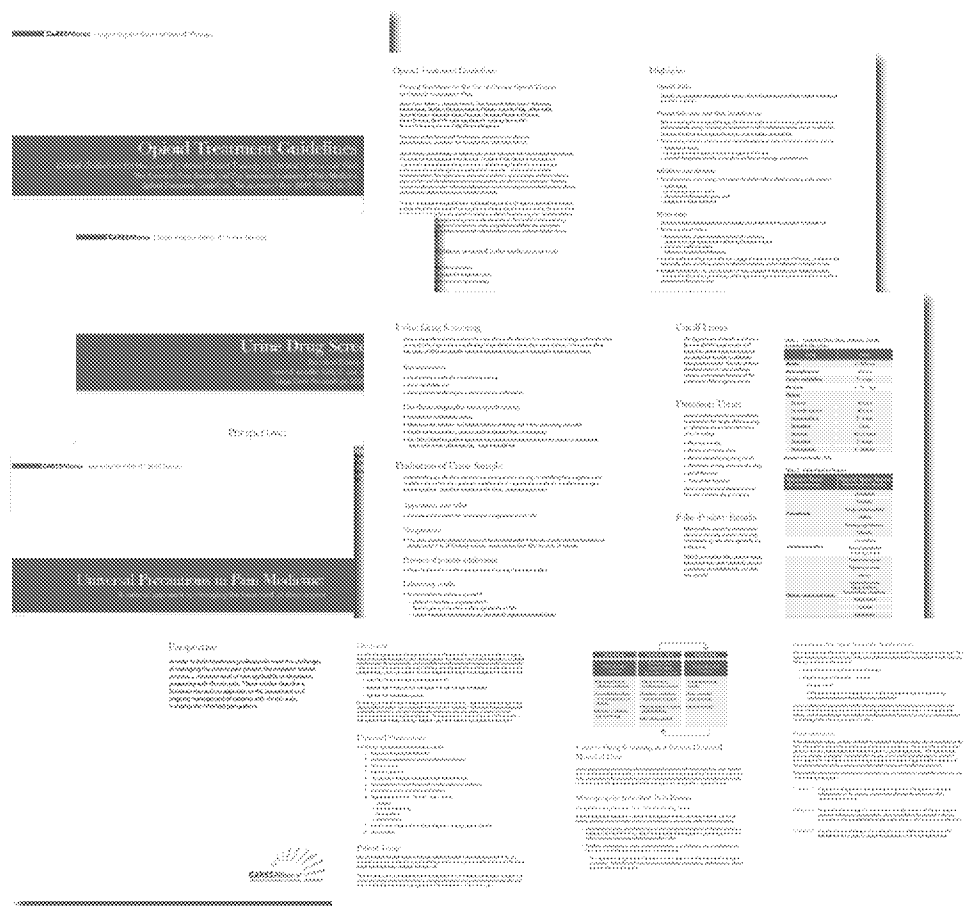


Figure 27: Patient-Prescriber Expectations and Responsibilities Form

Patient/Prescriber Expectations and Responsibilities Form

This form identifies the patient's expectations for treatment with a controlled substance and the prescriber's expectations for the patient's behavior. The form is completed by the prescriber and the patient. The form is completed by the prescriber and the patient. The form is completed by the prescriber and the patient.

Medical History and Current Status

☐ I have no other medical conditions or medications that could interact with my pain medication.
☐ I have no other medical conditions or medications that could interact with my pain medication.
☐ I have no other medical conditions or medications that could interact with my pain medication.

Current Medical History and Current Status

☐ I have no other medical conditions or medications that could interact with my pain medication.
☐ I have no other medical conditions or medications that could interact with my pain medication.
☐ I have no other medical conditions or medications that could interact with my pain medication.
☐ I have no other medical conditions or medications that could interact with my pain medication.
☐ I have no other medical conditions or medications that could interact with my pain medication.

My Physical and Mental Health

☐ I am not taking any other medications that could interact with my pain medication.
☐ I am not taking any other medications that could interact with my pain medication.
☐ I am not taking any other medications that could interact with my pain medication.
☐ I am not taking any other medications that could interact with my pain medication.
☐ I am not taking any other medications that could interact with my pain medication.

☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.

Side Effects and Other Concerns

☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.

Other Medication and Alcohol Use

☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.
☐ I will keep my pain medication secure and will not share it with anyone else.

Understanding Your Rights and Responsibilities

☐ I understand my rights and responsibilities when using a controlled substance.
☐ I understand my rights and responsibilities when using a controlled substance.
☐ I understand my rights and responsibilities when using a controlled substance.
☐ I understand my rights and responsibilities when using a controlled substance.
☐ I understand my rights and responsibilities when using a controlled substance.

Signature of Patient/Prescriber

Signature of Patient/Prescriber: _____ Date: _____

Signature of Prescriber

Signature of Prescriber: _____ Date: _____

Signature of Patient/Prescriber

Signature of Patient/Prescriber: _____ Date: _____

CARESPARTNERS
PAIN MANAGEMENT

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PAIN MANAGEMENT

5.1.8 Validated Pain Assessment Tools

The Numeric Rating Scale (NRS), Wong-Baker Faces Pain Rating Scale, and Brief Pain Inventory (BPI) are validated pain assessment tools for prescribers and patients that have been shown to be effective across a broad range of clinical pain conditions. The NRS and Wong-Baker are unidimensional pain scales that assess pain severity (Carr et al, 1992; Wong and Baker, 1988). The BPI is a multidimensional tool that assesses pain severity as well as the degree to which pain interferes with functioning (**Figure 28**) (Tan et al, 2004).

Figure 28: Validated Pain Assessment Tools

[illegible]

5.1.9 Validated Risk Assessment Tools

The Opioid Risk Tool (ORT) and the Revised Screener and Opioid Assessment for Patients with Pain (SOAPP[®]-R) are scientifically validated tools for prescribers that can assist in identifying patients who may develop aberrant drug-related behaviors based on known risk factors associated with abuse or addiction. The ORT is a brief, 5-question assessment that can either be self-administered by the patient or completed by the HCP as part of the patient interview to aid in patient selection with regard to risk assessment and stratification (Webster and Webster, 2005). The SOAPP-R is a brief paper and pencil tool intended to predict which patients being considered for long-term opioid therapy may exhibit aberrant medication-related behaviors in the future (**Figure 29**) (Butler et al, 2008).

Figure 29: Validated Risk Assessment Tools

Opioid Risk Tool Clinician Form

Score each question as follows:

Question	Answer	Score
1. Family History of Substance Abuse	Alcohol	11
	Illegal Drugs	15
	Prescription Drugs	19
2. Personal History of Substance Abuse	Alcohol	2
	Illegal Drugs	4
	Prescription Drugs	5
3. Age, Race, Sex, and Ethnicity	12	12
4. History of Physical Illnesses	15	15
5. History of Mental Illnesses	12	12
6. History of Social Problems	15	15
7. History of Legal Problems	15	15
8. History of Financial Problems	15	15
9. History of Employment Problems	15	15
10. History of Relationship Problems	15	15
11. History of Family Problems	15	15
12. History of Community Problems	15	15
13. History of National Problems	15	15
14. History of International Problems	15	15
15. History of Global Problems	15	15
16. History of Other Problems	15	15
17. History of All Problems	15	15
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100. History of All Problems	15	15

Opioid Risk Tool Patient Form

Score each item that applies:

Question	Answer	Score
1. Family History of Substance Abuse	Alcohol	11
	Illegal Drugs	15
	Prescription Drugs	19
2. Personal History of Substance Abuse	Alcohol	2
	Illegal Drugs	4
	Prescription Drugs	5
3. Age, Race, Sex, and Ethnicity	12	12
4. History of Physical Illnesses	15	15
5. History of Mental Illnesses	12	12
6. History of Social Problems	15	15
7. History of Legal Problems	15	15
8. History of Financial Problems	15	15
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16. History of Other Problems	15	15
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99. History of All Problems	15	15
100. History of All Problems	15	15

5.1.10 Validated Abuse Monitoring Tools

The Pain Assessment and Documentation Tool (PADT[™]) and the Current Opioid Misuse Measure (COMM[®]) are scientifically validated tools for use in patients on chronic opioid therapy. The PADT is a clinician-directed interview tool designed to help assess a patient's pain level and how well that pain is being managed by treatment (Passik et al, 2004). The tool also allows for the documentation of adverse events and potential aberrant behaviors. The COMM is a brief assessment tool intended to help clinicians identify whether a patient currently on long-term opioid therapy may be exhibiting aberrant drug-related behaviors associated with misuse of opioid medications (**Figure 30**) (Butler et al, 2007).

Figure 30: Validated Abuse Monitoring Tools

[illegible]

5.1.11 Online Resources Center

The print and video content for HCPs discussed above is available for viewing, download, and/or print ordering at the www.caresalliance.org website. This site functions as a one-stop resource for HCPs interested in opioid safety (**Figure 31**).

Figure 31: The C.A.R.E.S. Alliance Website Prescriber Resources Page

[illegible]

5.2 Independent Medical Education

Mallinckrodt supports numerous independent medical education programs that promote the responsible prescribing and safe use of opioid medications. This education is for prescribers, pharmacists, and patients and comprises live educational events, print material, and online activities. For more details about these individual programs, see Appendix D.

5.3 The C.A.R.E.S. Alliance Program

5.3.1 Opioid Safe Use and Handling Guide

The Opioid Safe Use and Handling Guide is an educational resource for patients that describes the serious risks, such as overdose, abuse, and addiction, as well as safe use instructions for prescription opioid analgesics (**Figure 32**). This guide also contains two additional tools, the My Meds Card and the Safe Use and Handling Card. These tools are perforated for the patient to tear out and carry (see below and Appendix D).

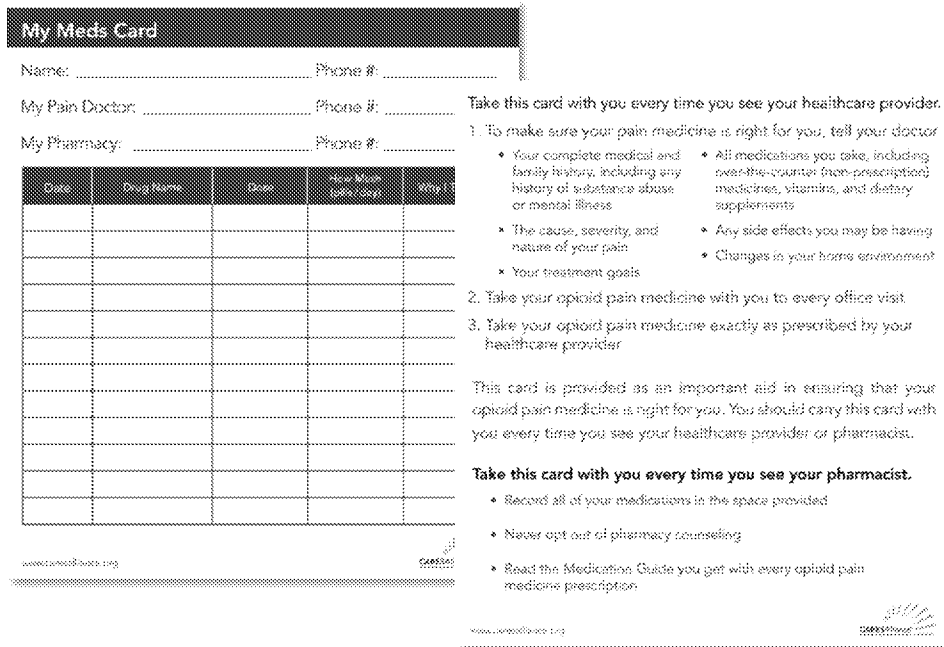
Figure 32: Opioid Safe Use and Handling Guide



5.3.1.1 My Meds Card

The My Meds Card is a tool that assists patients in keeping track of their medications. The card can be used to facilitate discussions with their HCP about the safe use of opioid medications (**Figure 33**).

Figure 33: My Meds Card



My Meds Card

Name: _____ Phone #: _____

My Pain Doctor: _____ Phone #: _____

My Pharmacy: _____ Phone #: _____

Date	Drug Name	Dose	How Much (pills/caps)	Notes

www.caresalliance.org

Take this card with you every time you see your healthcare provider.

1. To make sure your pain medicine is right for you, tell your doctor

- Your complete medical and family history, including any history of substance abuse or mental illness
- All medications you take, including over-the-counter, non-prescription medicines, vitamins, and dietary supplements
- The cause, severity, and nature of your pain
- Any side effects you may be having
- Your treatment goals
- Changes in your home environment

2. Take your opioid pain medicine with you to every office visit.

3. Take your opioid pain medicine exactly as prescribed by your healthcare provider.

This card is provided as an important aid in ensuring that your opioid pain medicine is right for you. You should carry this card with you every time you see your healthcare provider or pharmacist.

Take this card with you every time you see your pharmacist.

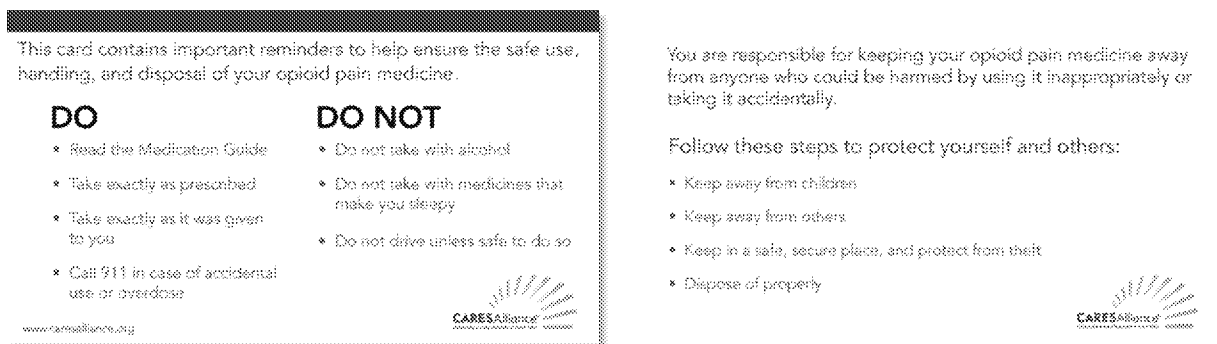
- Record all of your medications in the space provided
- Never opt out of pharmacy counseling
- Read the Medication Guide you get with every opioid pain medicine prescription.

www.caresalliance.org

5.3.1.2 Safe Use and Handling Card

The Safe Use and Handling Card provides important reminders for safe use of prescription opioids. The card is small enough to be kept in the patient's wallet (**Figure 34**).

Figure 34: Safe Use and Handling Card



This card contains important reminders to help ensure the safe use, handling, and disposal of your opioid pain medicine.

DO

- Read the Medication Guide
- Take exactly as prescribed
- Take exactly as it was given to you
- Call 911 in case of accidental use or overdose

DO NOT

- Do not take with alcohol
- Do not take with medicines that make you sleepy
- Do not drive unless safe to do so

www.caresalliance.org

You are responsible for keeping your opioid pain medicine away from anyone who could be harmed by using it inappropriately or taking it accidentally.

Follow these steps to protect yourself and others:

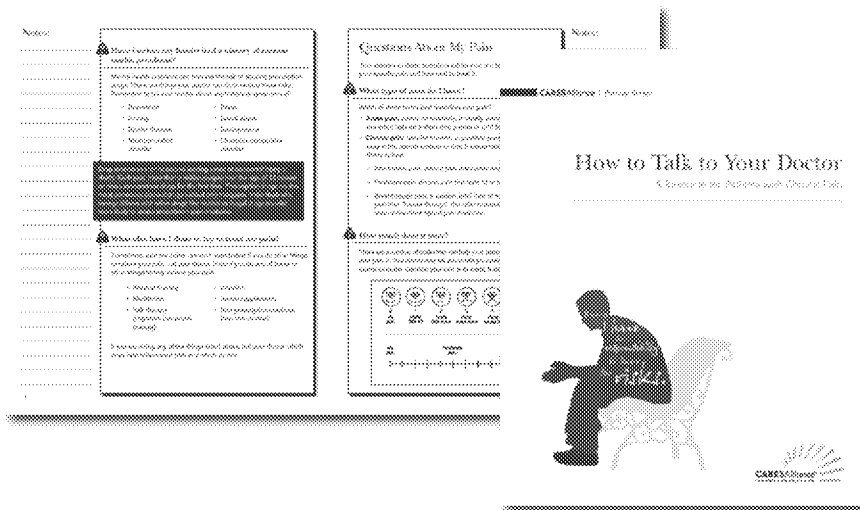
- Keep away from children
- Keep away from others
- Keep in a safe, secure place, and protect from theft
- Dispose of properly

www.caresalliance.org

5.3.2 How to Talk to Your Doctor Brochure

The How to Talk to Your Doctor Brochure for patients is an educational tool and workbook intended to facilitate interactions between patients and their HCP. The tool describes what patients should tell their doctors and what doctors can tell patients to optimize the clinical outcomes and safe use of prescription opioid analgesics (**Figure 35**).

Figure 35: How to Talk to Your Doctor Brochure



5.3.3 Pain Management Journal

The Pain Management Journal is a resource for patients that can assist them in tracking their pain and pain management. Filling out the journal can facilitate communication with the HCP, which will optimize the pain management regimen for both the patient and the HCP (**Figure 36**).

Figure 36: Pain Management Journal

